

### **REMARKS**

Claims 5-14, 19-22, and 24-29 are currently pending in this application. In the Office Action mailed May 21, 2008 (the "Office Action"), claims 5-14 and 19-27 were rejected. Through this response, claims 5-6, 19-20, and 22 are amended, claim 23 is cancelled and new claims 28-29 are added. No new matter has been added. Applicants respectfully request favorable reconsideration of the present application in light of the amendments to the claims and the following remarks.

The Applicant has amended independent claims 5, 19, and 22 herein to better define the subject matter sought to be patented. The amendment is made without prejudice and the Applicants reserve the right to pursue the original subject matter, for example, in a continuation application.

#### **Specification**

Through this amendment, Applicants have amended the specification with the addition of two new paragraphs. The material added to the specification through this amendment was incorporated by reference at the time of filing via the incorporation by reference of PCT App. Serial No. PCT/US02/22247, entitled "System and Methods for Determining Nerve Proximity, Direction, and Pathology During Surgery," filed July 11, 2002; PCT App. Ser. No. PCT/US02/30617, entitled "System and Methods for Performing Surgical Procedures," filed September 25, 2002; and PCT App. Ser. No. PCT/US03/02056, entitled "System and Methods for Determining Nerve Direction to an Instrument," filed on January 15, 2003. As such, no new matter has been entered through this amendment.

#### **New Claims**

Through this amendment Applicants have added new claims 28 and 29. New claims 28-29 are supported by the paragraphs inserted into the specification through this amendment. The added material was properly incorporated by reference at the time of filing and as such does not constitute new matter.

#### **Double Patenting**

Beginning on page 2 of the Office Action, claims 5-14 and 19-27 were rejected on

grounds of non-statutory obviousness type double patenting over various claims of US Patent 7,207,409 to Miles et al. ("Miles"). Miles is commonly owned with the present application. As such a terminal disclaimer is being filed herewith such that the rejection for double patenting should be withdrawn. An indication to that effect is respectfully requested.

Claims 5-14 and 19-27 were also provisionally rejected on grounds of non-statutory obviousness type double patenting over various claims of US Patent Application No. 10/444,917 to Bertagnoli et al. ("Bertagnoli"). Bertagnoli is commonly owned with the present application. As such a terminal disclaimer is being filed herewith such that the provisional rejection for double patenting should be withdrawn. An indication to that effect is respectfully requested.

The Applicants note that filing of a Terminal Disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection.

#### **Claim Rejections -35 USC 103(a)**

Claims 5-12, 14, and 19-27 were rejected under 35 USC 103(a) as being unpatentable over US Patent 4,545,374 to Jacobson et al. ("Jacobson") in view of US Patent 6,325,764 to Griffith et al. ("Griffith") in view of US Patent 4,562,832 to Wilder ("Wilder") in view of US Patent 6,306,100 to Prass ("Prass"). Additionally, claim 13 was rejected under 35 USC 103(a) as being unpatentable over Jacobson in view of Griffith in view of Wilder in view of Prass and further in view of US Patent Application 2002/0161415 to Cohen et al. ("Cohen").

To establish a *prima facie* case of obviousness under 35 USC § 103(a) in view of a reference or combination of references, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference(s) must teach or suggest all the claim limitations. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the

art.

Claim 5, as amended, recites a system for accessing a surgical target site. The system comprises an initial distraction system for creating an initial distraction corridor. The initial distraction assembly includes a K-wire and at least one dilator capable of being passed over said K-wire to perform the initial distraction. The system further comprises an assembly capable of being guided to the surgical target site along the at least one dilator of the initial distraction assembly and distracting from the initial distraction corridor to a secondary distraction corridor to create an operative corridor to the surgical target site. At least one of the initial distraction system and one of the retractor blades includes at least one stimulation electrode.

Claim 19, as amended, recites a method of accessing a surgical target site. The method comprises the following steps. Creating an initial distraction corridor through tissue extending between an incision point and a surgical target site via an initial distraction assembly. The initial distraction assembly includes a K-wire and at least one dilator capable of being slideably passed over said K-wire. Distracting the tissue from the initial distraction corridor to a secondary distraction corridor with an instrument capable of being guided to said surgical target site along the at least one dilator of the initial distraction assembly. Introducing a plurality of retractor blades for retracting the tissue from the secondary distraction corridor to create an operative corridor to said surgical target site. And, providing a control unit capable of electrically stimulating at least one stimulation electrode provided on the initial distraction assembly, sensing a response of a nerve depolarized by the stimulation, determining at least one of nerve proximity and nerve direction from the initial distraction assembly to the nerve based upon the sensed response, and communicating to a user at least one of visual indicia and audio communications representing at least one of said determined nerve proximity and said determined nerve direction.

Claim 22, as amended, recites a method of accessing a surgical target site, comprising the following steps. Creating an operative corridor through tissue extending between an incision point and a surgical target site via a distraction assembly and a retraction assembly. The distraction assembly comprises an initial assembly including an elongate inner element and at least one dilator. The distraction assembly further comprises a secondary instrument advanceable to the surgical target site along the at least one dilator of the initial assembly. At

least one of the distraction assembly and retraction assembly includes at least one stimulation electrode. Electrically stimulating at least one stimulation electrode. Sensing a response of a nerve depolarized by the stimulation. Determining at least one of nerve proximity and nerve direction of the nerve relative to at least one of the distraction assembly and the retraction assembly based upon the sensed response. And, communicating indicia to a user representing at least one of the determined nerve proximity and the determined nerve direction.

The Applicants respectfully submit that the Jacobson, Griffith, Wilder, Prass, and Cohen references, whether considered alone, or in combination, fail to contain the requisite teaching, suggestion, or motivation that would have led one of skill in the art to combine the references to achieve the present invention as claimed. At the very least, the references appear to be completely silent with regard to at least one element of claims 5, 19, and 22, such that the rejection under 35 U.S.C § 103(a) is improper and should be withdrawn

Jacobson discloses a system for accessing a spinal target site and is generally relevant to the claimed invention. However, Jacobson fails to teach of an initial distraction assembly that includes both a “K-wire and at least one dilator capable of being slidably passed over said K-wire,” in addition to an assembly or instrument “capable of being guided to said surgical target site along said at least one dilator of said initial distraction assembly,” to further distract from the initial distraction corridor to a secondary distraction corridor, as is required in claims 5 and 19. Likewise, Jacobson fails to disclose a distraction assembly that includes both an “initial assembly including an inner element and at least one dilator,” and a “secondary instrument advanceable to said surgical target site along said at least one dilator of said initial assembly,” as found in claim 22.

In the Office Action, the Examiner suggests that Jacobson discloses an initial distraction system (21, 24) for creating an initial distraction corridor and that the initial distraction system includes a K-wire (24) and an assembly (11) capable of distracting from the initial distraction corridor to a secondary corridor. The Applicants do not agree with this assertion. According to Jackson, an anesthetic needle (8 or 24) or other guide member of 3 mm diameter or less (e.g. a K-wire) is advanced to the spine of a patient. A specially designed speculum (20), including a pair of blades (21), is then advanced to the target site directly over the needle or K-wire (8, 24).

Upon reaching the spine, the blades (21) of the speculum are spread to create a channel. Only thereafter is a working cannula (11, 30), which is smaller than the channel created by spreading the speculum blades 21, placed through the channel. Subsequent to placing the cannula (11, 30) the speculum (20) is removed and the channel may close around the cannula (11, 30). *See Jacobson, col. 5, ln. 60 – col. 6, ln. 5, and Figs. 5-6.* Thus, the cannula (11, 30) is inserted only after any distraction of the operative corridor has already occurred. In fact, the cannula (11, 30) has the opposite effect of distraction in that the operative corridor gets smaller rather than larger due to the cannula. Jacobson thus discloses only a single guide member and a speculum for creating a distraction corridor to a surgical target and cannot be said to include both an initial distraction assembly comprising both **“a K-wire and at least one dilator** capable of being slidably passed over said K-wire” and an additional assembly or instrument “capable of being guided to said surgical target site **along said at least one dilator** of said initial distraction assembly,” for further distracting to a secondary distraction corridor, as is required in both claims 5 and 19. Similarly, Jacobson cannot be said to contain both the claim 22 limitations of having both an “initial assembly including **an inner element and at least one dilator,**” and a **“secondary instrument advanceable to said surgical target site along said at least one dilator** of said initial assembly,” as found in claim 22.

Griffith, Wilder, Prass, and Cohen do not fill the voids left by Jacobson. The Wilder reference is directed towards attaching light pipes to medical instruments, including retractors. And while Wilder does show a pair of retractors, Wilder does not appear to disclose an initial distraction assembly comprising both **“a K-wire and at least one dilator** capable of being slidably passed over said K-wire” or an additional assembly or instrument “capable of being guided to said surgical target site **along said at least one dilator** of said initial distraction assembly,” for further distracting to a secondary distraction corridor, as is required in both claims 5 and 19. Wilder is equally as silent with regard to the claim 22 limitations of having both an “initial assembly including **an inner element and at least one dilator,**” and a **“secondary instrument advanceable to said surgical target site along said at least one dilator** of said initial assembly,” as found in claim 22.

Griffith and Prass are generally related to neurophysiology systems for localizing peripheral nerves relative to a probe or needle cannula. Cohen is generally related to a

neurophysiology system for stimulating nerves to induce limb actuation of a paralyzed limb. None of these references teach or describe the limitations of claims 5, 19, and 22 described above, namely, an initial distraction assembly comprising both “**a K-wire and at least one dilator** capable of being slidably passed over said K-wire” or an additional assembly or instrument “capable of being guided to said surgical target site **along said at least one dilator** of said initial distraction assembly,” for further distracting to a secondary distraction corridor (claims 5 and 19) and having an “initial assembly including **an inner element and at least one dilator**,” and a “**secondary instrument advanceable to said surgical target site along said at least one dilator** of said initial assembly,” (claim 22).

Applicants thus respectfully submit that the Jacobson, Wilder, Griffith, Prass, and Cohen references, whether taken alone or in combination fail to contain the requisite teaching that would have led one of ordinary skill in the art to the present invention as set forth in claims 5, 19, and 22, such that the rejection under 35 USC 103(a) is improper and should be withdrawn. Claims 5, 19, and 22 are believed to be in proper condition for allowance and an indication to that effect is respectfully requested.

Claims 6-14 and new claim 28 are dependent upon claim 5 and should be allowable at least for the reasons set forth with regard to the allowability of claim 5, as well as the additional limitations they contain, and an indication to that effect is requested. Claims 20-21 and new claim 29 are dependent upon claim 19 and should be allowable at least for the reasons set forth with regard to the allowability of claim 20, as well as the additional limitations they contain, and an indication to that effect is requested. Finally, claims 23-27 are dependent upon claim 22 and should be allowable at least for the reasons set forth with regard to the allowability of claim 30, as well as the additional limitations it contains, and an indication to that effect is requested.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this

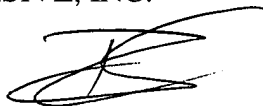
paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment

### **CONCLUSION**

The foregoing amendment has been submitted to place the present application in condition for allowance. Favorable consideration and allowance of the claims in this application is respectfully requested. The Applicant hereby authorizes a payment of the \$555.00 fee for the 3 month Extension of Time, the \$140.00 fee for the filing of two terminal disclaimers, and the \$26.00 fee for one extra claim, to be charged to Deposit Account No.: 50-2040 for Customer No.: 30,328. No other fees are deemed necessary at this time. However, in the event that there are any additional fees to be charged or payments to be credited, the Applicant hereby requests that any charges or credits be made to Deposit Account No.: 50-2040 for Customer No.: 30,328. In the event that there are any questions concerning this Amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,  
NUVASIVE, INC.

By: \_\_\_\_\_

  
Rory Schermerhorn, Esq.  
Registration No. 58,148

7475 Lusk Boulevard  
San Diego, CA 92121  
Tel: (858) 909-1845

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